REMARKS

Claims 14, 16 and 23-27 are pending and stand ready for further action on the merits. Claims 26 and 27 have been withdrawn from consideration as being drawn to non-elected subject matter.

Election/Restriction

The Examiner has imposed a Restriction Requirement. Specifically, the Examiner has indicated that claims 26-27 have been withdrawn from consideration as being drawn to non-elected subject matter. The Examiner has restricted the claims into the following two groups:

Group I - Claims 14, 16 and 23-25; and

Group II - Claims 26 and 27.

In restricting Groups I and II, the Examiner indicates that the inventions of Groups I and II are related as product and process of use, respectively. The Examiner cites MPEP § 806.05(h) for authority in restricting these groups. Specifically, the Examiner states as follows:

> [t]he inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

> using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Applicants traversal is based on the fact that the Examiner is inappropriately restricting the invention under U.S. restriction practice and not Unity Of Invention rules.

Applicants respectfully submit that the Examiner's analysis is appropriate for applications filed under 35 USC 111, and is not appropriate for 371 applications such as the present application.

Applicants respectfully traverse the restriction requirement and request that Group II be rejoined with group I, since there is a *single general inventive concept* in Groups I-II. Specifically, the single general inventive concept is an ointment consisting of acetyl salicylic acid wherein the ointment does not contain water for dissolving said acetyl salicylic acid.

Based upon the decision in Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks, 231 USPQ 590 (E.D. Va. 1986), the Patent and Trademark Office now must consider applications filed under 35 USC 371, by following PCT Rule 13.1 and 13.2 when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 USC 111.

The MPEP instructs (at page 1800-67, column 1, revised Feb. 2003), that the

> method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, ... and an independent claim for a use of the said product...

Thus, it is proper to keep the methods and products together, since the special technical feature (an ointment consisting of acetyl salicylic acid wherein the ointment does not contain water for dissolving said acetyl salicylic acid) is common to each of Groups I-II.

In the absence of an appropriate rationalization, Applicants respectfully submit that the Restriction Requirement set forth by the Examiner is not tenable. Thus, Applicants respectfully request that the Examiner rejoins Groups I and II.

Issues Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 14, 16 and 23-25 under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse the rejection.

Specifically, the Examiner has taken the position that the concentration ranges of 20-30 wt. % and 25-30 wt. % as described in the last clause of claim 14, constitute new matter.

In response, Applicants respectfully submit that there is sufficient written description support in the original disclosure. Specifically, the range of 20-30 wt. % can be found by combining the range of 0.001-30 wt. % with the range of 0.01-20 wt. %, both of which are disclosed on page 3, line 15 of the present specification.

Also, the range of 25-30 wt. % can be found by combining the range of 0.001-30 wt. % as disclosed on page 3, line 15 with the lower limit of 25 wt. % as would be found from the example given on page 6, lines 5-8 of the present specification.

Accordingly, no new matter has been added to the disclosure by way of the July 7, 2003 Amendment to claim 14. Since Applicants were in possession of the invention described in presently amended claim 14 as of the instant priority date, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Issues Under 35 U.S.C. § 103

The Examiner has imposed the following two rejections:

(A) claims 14, 16 and 23-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Burton, U.S. 4,012,508; and

(B) claim 25 is rejected under 35 U.S.C. §103(a) as being unpatentable over Burton in view of Konishi et al., U.S. 5,916,918.

Applicants respectfully traverse each of the rejections.

With regard to the teachings of Burton, the Examiner is relying upon the disclosure at column 2, lines 6-9 which reads as follows:

> [g]enerally, about 5 to 20 parts by weight of the mixture will be used with 100 parts of the carrier. The mixture can be even lesser amounts when the composition is used on diabetics.

This range of 5 to 20 parts by weight of Aspirin per 100 parts of carrier is equivalent to 4.8-16.7 wt.% Aspirin.

The Examiner also notes that in the examples of Burton, Aspirin is incorporated into the ointment at about 50 wt.%.

Applicants respectfully take the position that the ointment defined in independent claim 14 is distinct from the ointment of Burton, since: 1) the ointment of Burton requires a cortical steroid be placed with the Aspirin, whereas independent claim 14

does not include a cortical steroid in view of the recitation of the transitional phrase "consisting of;" and 2) the only example of Burton which does not include the cortical steroid is Example 10, which is a "comparative" example that includes Aspirin in a concentration well out of the inventive concentration range of about 25% to 30% by weight. In Comparative Example 10 of Burton, the concentration of Aspirin is approximately 53%.

Furthermore, Applicants respectfully submit that Example 10 of Burton is a comparative example and is only presented to show the **disadvantages of not including a cortical steroid** in the composition for treating the specific skin disorders of corns, warts, calluses and athlete's foot, see column 1, lines 6-8. As can be seen from column 1, lines 30-32, the ointment of Burton must include the cortical steroid to be effective. This is further evidenced by the fact that the ointment of Example 10, not having the cortical steroid, was totally ineffective. Specifically, Burton states:

> [a]fter six days of treatment, the skin appeared to be loose but the corns remained and the affected area was so sore that treatment could not be continued.

Thus, the comparative Example 10 of Burton is a teaching away from the presently claimed ointment which does not include a cortical steroid.

A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. *Dow Chem. Co. v. American Cyanamid Co.* 816 F2d 617, (CAFC 1987). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention." *Akzo N.V. v. United States Int'l Trade Comm'n*, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986); *In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988).

The Examiner states,

> [i]t is deemed obvious to one of ordinary skill in the art to look to the teachings of Burton and manipulate the amount of Aspirin in the composition. One would be motivated to do so since Burton teaches a general guidance of the amount of Aspirin in the composition but teaches that this can be manipulated **based on what is desired**. (Emphasis added).

Applicants believe that the Examiner has correctly indicated that the skilled artisan would manipulate the amount of Aspirin in the composition "based on what is desired;" however, there is nothing in Burton to show that Aspirin in the range of 20%-30% by weight

would be desirable. There is generic guidance that the concentration of Aspirin can be in the range of 4.8-16.7 wt% when used in combination with a steroid. However, as mentioned above, the use of a steroid is excluded from the claims in view of the transitional phrase, "consisting of."

Accordingly, the artisan must rely on the single example which does not include steroids in the composition, i.e., Example 10, to find what would be desirable. This example shows that Aspirin is still ineffective in a concentration as high as ~53wt% unless it is used in combination with a steroid. Thus, it would be desirable to the skilled artisan to use ointments in a concentration higher than 53% to test for a therapeutic effect, not lower than 53% as asserted by the Examiner.

At most, modifying the concentration of the Aspirin used in the examples of Burton to be within the inventive range of 20-30 wt%, would be "obvious to try" to the skilled artisan. The courts have determined that the "obvious to try" standard does not meet the requirements for obviousness under 35 USC 103. *In re Tomlinson*, 150 U.S.P.Q. 623 (C.C.P.A. 1966). In *In re O'Farrell*, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988), the Federal Circuit gave some examples of what would constitute an "obvious to try" modification based on the prior art noting that "[i]n some cases, what would have been

'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possible arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."(citations omitted).

Since the "obvious to try" standard is not sufficient to reject claims under 35 U.S.C. § 103, this rejection is not tenable.

In addition, the Examiner notes that Burton teach that the amount of Aspirin in the ointment can be reduced when the ointment is to be used on diabetics (see the disclosure of Burton which is reiterated above). Applicants respectfully submit that this teaching would be viewed by the skilled artisan as being relevant to the concentration of Aspirin when the Aspirin is combined with steroids. Since Burton has shown in Comparative Example 10 that Aspirin without steroids is ineffective even at a concentration of ~53wt%, the skilled artisan would have no reason to believe that reducing the concentration to less than 53wt% would give a therapeutic effect.

Based on the foregoing, Applicants respectfully submit that significant patentable distinctions exist between the present invention and the teachings of Burton.

The Examiner, aware of the deficiencies of Burton, cites Konishi et al. in order to cure those deficiencies. Applicants respectfully submit that Konishi et al. fail to cure the deficiencies of Burton. Specifically, the Examiner cites Konishi et al., for teaching that a hydrocarbon gel (plastibase) can be used as a replacement for the carrier of Vaseline taught by Burton. Accordingly, the teachings of Konishi et al. do not cure the deficiencies of the teachings of Burton. As the MPEP directs, all the claim limitations must be taught or suggested by the prior art to establish a *prima facie* case of obviousness. See MPEP § 2143.03. Applicants respectfully submit that a *prima facie* case of obviousness cannot be said to exist, since Burton and/or Konishi et al. fail to teach or fairly suggest the inventive concentration range of Aspirin of 20-30 wt. % or 25-30 wt. %, as presently claimed. As such, withdrawal of each of the rejections are respectfully requested.

Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. A Notice to such effect is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Marc S. Weiner, #32,181

MSW/GMD/bsh
20-4518P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000